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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,734	12/28/2001	Steven J. Brattesani	BRA1633.45A	7454

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EXAMINER

MANAHAN, TODD E

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 03/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/033,734

Applicant(s)

BRATTESANI ET AL.

Examiner

Todd E. Manahan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5, 12, and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification, as originally filed, does not disclose that the color changing material “only” changes color when contacting particular enzymes in a mouth at vivo temperature range. Such recitation therefore constitutes new matter, which is not permitted.

Claims 4, 5, 11, 12, 18, 19, and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification fails to adequately disclose the color changing materials, which change color upon reaction with enzymes in the mouth. Without knowing what materials to use, one skilled in the art would be unable to make and/or use the embodiment of the invention in which the floss is coated with a material that changes color upon reaction to enzymes. It is also unclear what these

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materials are which would change color **only** in the mouth and not in any other environment (such as a laboratory) when contacted with the same enzymes, as is now claimed.

Claims 23-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for color changing material that changes color as the result of removal, in response to pH, and when it is thymol blue or bromthymolphthalein, does not reasonably provide enablement for color changing material that changes color as a result of reaction with enzymes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 41 provides for the use of an enzyme detector to detect diabetes, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

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Claim 41 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8, 15, and 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Guay et al. (United States Patent No. 5,941,256).

Guay et al disclose dental floss, which has been coated or impregnated. The coating may comprise a material, which changes color to indicate usage as well as an active ingredient which may be used as a carrier for the pigment (see col. 4, line 63 through col. 5, line 14). It is to be understood that when the active ingredient is the carrier of the pigment, the dental floss will change color “through removal of the colored material from the colored dental floss”.

Claims 1, 8, and 15 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Pelok (United States Patent No. 5,732,721).

Pelok discloses dental floss impregnated with a pressure sensitive dye. The pressure sensitive dye may be a pH indicator. The pressure sensitive dye is released upon application of

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friction in which dye is removed from the floss. Application of the dye will cause the floss itself to change color

Claims 1, 8, 15 and 22 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Tseng (United States Patent No. 5,906,834).

Tseng disclose release matrixes that include a colorant and a water-leachable substance that causes the matrix to change color when exposed to water to indicate usage. (see col. 1, lines 53-59 and col. 3, lines 31-64). The matrix can be used to coat dental floss (see col. 3, line 18 and col. 11, lines 48-52).

Claims 6, 13, 20, 36 and 38 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Gathani (United States Patent No. 5,357,989 cited by applicant).

Gathani discloses dental floss that is coated with a color changing pH indicator. The coating on the floss changes color to specifically identify cariogenic bacteria in dental plaque (see col. 1, lines 8-15).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tseng.

To place the floss of Tseng on a spool would have been obvious as it is old and well known in the art to provide dental floss on a spool for convenient storage and dispensing.

Claims 2, 3, 9, 10, 16, 17, and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pelok.

Pelok discloses the claimed invention except for the pH indicator changing through the range of 5.0 to 9.0. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a pH indicator that changes through the range of 5.0 to 9.0, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Regarding claims 3, 10, and 17, to use either thymol blue or bromthymolphthalein as the pH indicator would have been obvious, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416. Regarding claims 23-26, place the floss on a spool would have been obvious as it is old and well known in the art to provide dental floss on a spool for convenient storage and dispensing.

Claims 37, 39, 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gathani.

To use a cancer detecting agent in the coating instead of the plaque detecting agent would have been obvious to one skilled in the art if one wished to detect oral cancer rather than detect the presence of plaque. Regarding claim 39, to use fluorescein sodium as the plaque detector would have been obvious, since it has been held to be within the general skill of a worker in the

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art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416. Regarding claims 42 and 43, to provide the floss with flavors or scents would have been obvious to one skilled in the art as such is old and well known in the art.

Claims 7, 14, 21, and 29-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kent et al. (United States Patent No. 4,986,288).

Kent et al disclose nylon floss directly coated or impregnated with a medicament, Kent et al however do not disclose placing the floss on a spool. To place the floss on a spool would have been obvious to one skilled in the art as it is old and well known in the art to provide dental floss on a spool for convenient storage and dispensing.

Response to Arguments

Applicant's arguments with respect to claims 1-43 have been considered but are moot in view of the new ground(s) of rejection.

In response to applicant's arguments regarding the Guay et al patent, Guay et al disclose using the active ingredients as a carrier for the color change pigment. The active agents are released or removed from the floss during flossing, and thus the pigment would be removed as well. (see col. 4, line 63 through col. 5, line 14). It is agreed that Guay et al do not disclose pH indicators as now recited in claims 2, 3, 9, 10, 16 and 17 or medicaments directly impregnated on the floss as set forth in claims 7, 14, 21 and 29.

In response to applicant's arguments regarding the Gathani reference, Gathani et al. disclose that the pH indicator dye specifically detects and identifies the presence of cariogenic bacteria and/or plaque (col. 1, lines 8-15). It is agreed that the pH indicators of Gathani do not

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change colors throughout the pH range of 5.0 to 9.0 as set forth in claims 2, 9 and 16. Gathani et al. also do not disclose the floss being directly coated or impregnated with a medicament or being disposed on a spool as recited in claims 29-35.

The rejections using Tarrson et al. and Dolan et al. have been overcome by amendments to the respective claims as clearly pointed out on pages 14 and 15 of applicant's remarks filed 09 January 2004.

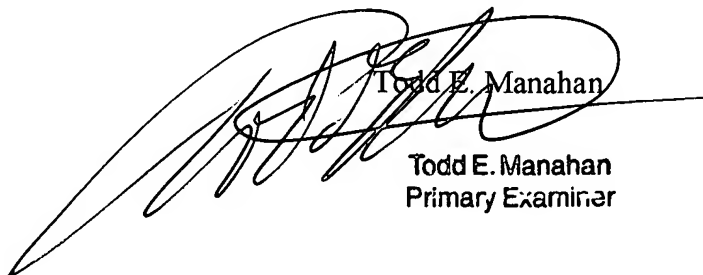
Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd E. Manahan whose telephone number is 703 308-2695. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on 703 308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Todd E. Manahan
Todd E. Manahan
Primary Examiner